

PHARMACY BOARD DRAFT EMERGENCY REGULATIONS

*all new language in bold; deleted language in strike-through

A. Existing Section; 2.00 Definitions - adds reference to specific definitions in new section 6.15

Additional definitions pertaining to:

- (1) nuclear pharmacies are contained in 247 CMR 13.00;
- (2) disciplinary proceedings are contained in 247 CMR 10.00;
- (3) continuous quality improvement programs are contained in 247 CMR 15.00; and
- (4) duty to report certain factors of pharmacy operations are contained in 247 CMR 6.15.**

B. New Section 247 CMR 6.15 – Duty to Report Certain Factors of Pharmacy Operations

(1) Definitions:

- (a) **Accreditation** means a process by which a professional association or non-governmental agency grants recognition to a pharmacy for demonstrated ability to meet certain pre-defined criteria.
- (b) **Disciplinary actions** means actions including, but not limited to revocation, suspension, probation, censure, reprimand, or restriction of the license to operate a pharmacy or practice pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency.

- (c) **Federal agency** means any U.S. Government agency that has regulatory purview over the clinical practice of pharmacy or of pharmacy operations, including, but not limited to, all agencies in the U.S. Department of Health and Human Services, the U.S. Occupational Safety and Health Administration, and the U.S. Department of Justice.
- (d) **State agency** means any U.S. State or Territory that licenses or otherwise regulates pharmacies or pharmacist practice.
- (e) **Sterile compounding** means the preparation, mixing, assembling, packaging, and labeling of a drug or device that is required to be prepared in accordance with United States Pharmacopeia Standard 797 and pursuant to a valid prescription as defined by M.G.L. c. 94C.

(2) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall report to the Board within 7 business days of receipt, in a manner and format determined by the Board, all non-routine notices, correspondence, and disciplinary actions as defined herein.

(3) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall report to the Board any adverse change in status of accreditation, including but not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning. All such reports shall be made within 7 business days of an action taken by the accrediting agency, and in a manner determined by the Board.

(4) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall provide the Board with responsive documents sent from a

registrant or licensee to a state or federal agency with respect to reports or responses submitted pursuant to 247 CMR 6.15 (2) and (3).

(5) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, that performs central intravenous admixture services (CIVAS), or engages in sterile compounding, shall report to the Board every six months, or upon request by the Board, at a minimum, the following information:

(a) total number of prescriptions dispensed, distribution data identifying the states in which the prescriptions were distributed, status of any non-resident licenses issued by other states, hood certifications required by 247 CMR 6.01(5)(c) 5, status of CIVAS approval(s) where applicable, and any other information required by the Board.

(b) All such reports shall be accurate and comply with the Board's reporting requirements.

(c) All reports shall be accompanied by an affidavit attesting compliance with all laws and regulations pertinent to sterile compounding. This attestation shall be made under pains and penalties of perjury, and include attestation to the following "this registrant/licensee only prepares and dispenses medication pursuant to a valid prescription as defined in M.G.L. c. 94C for a single patient, regardless of whether the medication is prepared for a Massachusetts or out-of-state patient."

(6) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall report within 7 business days all adverse events relating to preparation of medications in that pharmacy.

(7) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall

report within 7 business days all abnormal results, including failure of certification as required pursuant to 247 CMR 6.01(5)(c), and identification of environmental contaminants in that pharmacy as required pursuant to 247 CMR 9.01 (3).

(8) Failure to comply with reporting requirements described in 247 CMR 6.15 (2) – (7) or to cooperate fully in the Board’s investigation of any such report to the Board shall be grounds for disciplinary action pursuant to 247 CMR 10.03(1)(q).

C. Existing Section; 6.01 (5)(c) adds to subsections regarding reporting to the Board and maintenance on-site of approval letters

6.01 (5)(c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) shall, in addition to the 300 square feet required by 247 CMR 6.01(5)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. **The pharmacy shall obtain approval from the Board indicating compliance with these requirements prior to initial operation of central intravenous admixture services. The Board’s approval shall be posted conspicuously, visible to the public, on the pharmacy premises.** This clean room shall meet the following requirements:

D. Existing Section; 10.02 adds new definition of conviction; 10.03 adds penalties regarding failure to report; 10.06 adds delegation provision for Board action and adds new definitions of cease and desist and quarantine notices

Revises 247 CMR 10.02(1) by inserting new definition (Conviction) below after Complaint:

Conviction shall include any guilty verdict or finding of guilt and any admission to or finding of sufficient facts to warrant a finding of guilt, regardless of adjudication, a continuance without a finding, and any plea of guilty or *nolo contendere*, of or to a crime in any jurisdiction, which has been accepted by the court, whether

or not a sentence has been imposed. A conviction of any person licensed or registered by the Board shall be conclusive evidence of the commission of that crime in any disciplinary proceeding against such person based upon the conviction.

Revises 247 CMR 10.03(1)(w) by deleting “and” appearing at the end of the section with no substitution therefor:

Failing to comply with recognized ethical standards of the profession, including, but not limited to, the standards of practice of pharmacists, pharmacy interns, pharmacies and pharmacy departments set for in 247 CMR 9.01: Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments; ~~and~~

Revises 247 CMR 10.03(1)(x) by deleting “.” appearing at end of the section and inserting “;” therefor:

Violation of M.G.L. c. 94C or any rules or regulations promulgated thereunder;;

Revises 247 CMR 10.03(1) by inserting new subsections (y), (z) (aa), and (bb) below:

(y) Failing to report or failing to accurately report to the Board in writing, within 30 days, any disciplinary action (247 CMR 10.06) taken against a registrant or licensee by an entity or its agent, including but not limited to, a governmental authority, a health care facility, an employer, or a professional pharmacy related society (international, national, state or local), on the basis of actions listed in 247 CMR 10.03 (1);

(z) Failing to report to the Board, in writing, within 30 days, any final action (including license surrender or resignation) regarding a registrant or licensee, including any against any other health care related professional registration or license

held by a registrant or licensee, by any other governmental authority in this state or another jurisdiction;

(aa) Failing to report to the Board, in writing, within 30 days, any pending criminal charge or conviction, as defined in 247 CMR 10.02, of a registrant or licensee, in Massachusetts or any other jurisdiction;

(bb) Failure to comply with reporting requirements described in 247 CMR 6.15 (2) – (7) or to cooperate fully in the Board’s investigation of any such report.

Revises 10.06; Disciplinary Action

Actions which may be taken by the Board ~~after investigation of a complaint~~ are:

(8) Summary Cease and Desist Notice. A summary cease and desist notice may be imposed by the Board or Board President prior to hearing in order to stop or restrict operations by a registrant or licensee to immediately protect the public health, safety or welfare.

(9) Summary Quarantine Notice. A summary quarantine notice may be imposed by the Board or Board President prior to hearing in order to prevent the use of medications prepared by or in possession of a registrant or licensee to immediately protect the public health, safety or welfare.

E. (New Section) 10.08: Summary Cease and Desist and Quarantine Notice

(1) If, based upon affidavits or other evidence, the Board or Board President determines that a registrant or licensee or the products prepared by a registrant or licensee are an immediate or serious threat to the public health, safety, or welfare, the Board or Board President may:

- (a) issue a Cease and Desist Notice and/or Quarantine Notice, requiring cessation or restriction of any and all pharmacy operations, and prohibiting the use of medications prepared by or in possession of a pharmacy**
 - (b) issue a Cease and Desist Notice placing non-disciplinary restrictions on a Board registrant or licensee, to the extent necessary to avert a continued threat, pending final investigation results.**
- (2) Requirements of the Cease and Desist Order and/or Quarantine Notice shall remain in effect until the Board rescinds such requirements or until such time as the Board takes final action on any related pending complaint and the Board issues a final decision.**
- (3) A hearing limited to the determination of the necessity of Notices issued pursuant to 247 CMR 10.08 (1) shall be afforded the registrant or licensee within 21 days of the Board or Board President's action.**